CONSENT FORM

Study title: Genetic Epidemiology of Prostate Cancer in Africa

Principal Investigator:

FOR OFFICE USE ONLY

ID#: _____

Date: _____

Please read this form carefully. It provides important information about a research study that we would like to talk with you about.

In order to make an informed decision about whether or not you want to be a part of this study, you should understand the risks and benefits of participation.

If you decide to take part in this research study, you will be asked to sign at the end of this form to show that you wish to take part.

Why is this research study being done?

We want to understand what causes prostate cancer. We hope that the knowledge we gain from this research will lead to improved prevention, diagnosis, and treatment of prostate cancer.

We are studying men diagnosed with prostate cancer (cases) and men who do not have prostate cancer (controls) in Ghana, Nigeria, Senegal, South Africa, and the USA.

This consent form gives you information about the risks and benefits of the study so that you can decide whether or not you want to be a part of this research.

Our research is funded by the US National Institutes of Health (NIH). We expect to enroll 500 cases and 500 controls in this research study per year of this five year study. Operating across six recruitment sites in Africa, the study is planning to recruit a total of 2,450 newly diagnosed patients with prostate cancer and 2,450 men without prostate cancer (controls).

No formal genetic counseling will be provided as part of this study.

What are we asking you to do?

We would like you to:

1) Fill out a questionnaire.
2) Allow us to get information about your health from your medical record.
3) Donate 20cc blood, saliva or a cheek swab sample. From these samples, we will extract DNA for laboratory studies so that we can learn about the genetics of cancer. The genetic information obtained will be used for research purposes only.
4) Allow us to store your sample for future studies, and to share it with other researchers.

Will this study cost you anything?

Participating in this study is done at no cost to you. You will not be paid or otherwise compensated if you take part in this study. Results will be kept completely confidential, except as required by law. Your biosample and questionnaire will be given a code number. Information obtained from this study will be identified, stored, and published using that code only. Participation in this study is voluntary. No compensation for participation will be given.

How much time will this study take?

Your participation in this study should take no more than one hour.

What are the risks of the study?

Taking blood for this study can cause minor discomfort, bruising, fainting, and infection. There is no risk associated with providing a saliva, mouthwash or cheek swab sample.

How do we protect your information?

There are many safeguards in place to protect your information, sample(s) and privacy. The information you share with us will remain completely confidential. Information collected from you during this study will be given a unique code and your identity will not be shared with anyone except study staff.

Who, outside of this hospital might receive your personal, genetic and health information?

Biosamples (DNA, samples), genomic and questionnaire data may be shared with research teams outside of your Hospital. If your sample(s) and/or data are shared with other researchers or institutions in the future, your information will be labeled with a research code such that you cannot be identified. You will not be identified by name, address, telephone number, or any other personal identifier, unless disclosure of the direct identifier is required by law. Genetic information will be stored in a secure database that may be accessed by authorized researchers.

Your name or personal information will only be available to research staff. If you have questions about storing of samples or would like to request that samples be removed from storage, you may contact the Principal Investigators listed. It is not always possible to remove samples from storage or to retrieve samples that have already been sent to other investigators. Results obtained prior to your sample removal request will remain part of the study.

Will any of the samples (blood, DNA) taken from me be used for future research studies?

Yes, blood and DNA samples will be stored for future research studies. These biological samples, taken from your body, may be used for future research studies; however your name, address, personal or protected health information will NOT be disclosed to anyone. At this time, the researchers do not know what the future studies will be. Your specimens may also be submitted to a tissue/cell/DNA bank. The specimens may be kept for a long time.

How will I benefit?

There may be no personal benefit resulting from donation of a biosample, or from completing the questionnaire. However, if you participate, many men may benefit if we can learn how to better prevent or treat cancer.

What if I have questions?

After reading this form and having a discussion about what it says, you should ask all the questions you want to ask. You should take as much time as you need to make a decision. If you do not understand some of the terms used in this form, ask the person who is discussing the study with you to give any additional information that may make this easier to understand. You do not have to consent to participate in the study immediately, or ever. Please take time to decide whether or not you wish to join. If you decide not to participate the care providers at this facility will give you all of the standard care that is appropriate for you. You will be given a copy of this form whether or not you agree to participate in this study. Do not sign the form unless you have had all your questions answered and understand exactly what is involved. If you have additional questions you may contact:

Name: _____

Role on study: _____

Phone number: _____

Documentation of Informed Consent and Authorization:

I have read this consent form and was given enough time to consider the decision to participate in this research.
This research has been satisfactorily explained to me, including possible risks and benefits.
All my questions were satisfactorily answered.
I understand that participation in this research is voluntary and that I can withdraw at any time.
I am signing this consent form prior to participation in any research activities.

Participant Signature:_____

Date (DD/MM/YYYY):_____

Investigator/Associate Signature:_____

Date (DD/MM/YYYY):_____

Please indicate your choice by initiating one (1) of the following options:

____ I consent to have my specimens used for future research studies.

____ I consent to have my specimens used for future research studies only for the study of_____.

____ I do NOT consent to have my specimens used for future research studies. (The specimens will be destroyed at the end of the study).

This research has been approved by _____.

If you have questions regarding your rights as a research subject, the Chairman of the Ethics Committee can be contacted at _____. The phone number is _____.